

Notice of Allowability

Application No.

09/760,046

Examiner

Humera N. Sheikh

Applicant(s)

MATHIOWITZ ET AL.

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 27 September 2005.
2. ☒ The allowed claim(s) is/are 1,3,4,6-13,15-23,25,26,34 and 35.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

7. ☒ The Drawings filed 9-16-02 are accepted by the Examiner.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

DETAILED ACTION

Status of the Application

Receipt of the Amendment after Final Response and Applicant's Arguments/Remarks, both filed 09/19/05 and the Notice of Appeal and request for extension of time, both filed 09/27/05 is acknowledged.

Claims 1, 3, 4, 6-13, 15-23, 25, 26, 34 and 35 are pending. Claims 2, 5, 14, 24 and 27-33 have previously been cancelled.

Allowable Subject Matter

Claims 1, 3, 4, 6-13, 15-23, 25, 26, 34 and 35 are allowed.

The following is an examiner's statement of reasons for allowance:

The primary reasons for allowance are that the prior art (Shah WO 98/46212) do not disclose nor fairly suggest or teach the instantly claimed method steps for micronizing an agent. In stark contrast, the prior art teaches a process for encapsulating proteins rather than a method for micronizing an agent as instantly claimed. The prior art also does not disclose following a lyophilization step with a step that dissolves the encapsulating polymer in a solvent to form a dispersion of solid microparticles of agent in the solvent. Such a step defeats the purpose of the prior art's (Shah WO '212) method, because it would destroy the solid encapsulating material. In contrast, this particular step is recited and required in instant claim 1.

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The instant invention demonstrates an improvement over prior art formulations because it provides for a method for obtaining micronized particles (*i.e.*, particles of proteins) and a method of making such particles which substantially avoids or minimizes denaturation of proteins. The instantly claimed method provides for stabilization of the agent as well as the production of very small particles having a uniform size, with minimal or no aggregation. The process yields microparticles having a homogeneous size distribution, whereby the microparticles have well defined, predictable properties, which is particularly critical in drug delivery applications. Thus, in view of the superior results demonstrated by the instant invention and the deficiencies of the prior art, the instant invention is rendered non-obvious and *patentable* over the cited art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh



Patent Examiner

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September 30, 2005



THURMAN K. PAGE
SUPERVISOR, PATENT EXAMINER
TECHNOLOGY CENTER 1600